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436 Woodland Terrace, SE Norton, VA 24273 March 10, 1999

Dockets Management Branch (HFA-305) Docket No. 98-N-1265 Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

I recently learned that the FDA is currently considering legislation that will restrict the ability of pharmacies to ship compounded prescription medications for personal use across state lines. I certainly hope the FDA will not take away my choice of getting the medications that have helped me deal with surgical menopause and the resulting INSOMNIA, HOT FLASHES, NIGHT SWEATS, CONCENTRATION DIFFICULTY, FATIGUE much more successfully than the standard medications I used for many years with limited success. There are no compounding pharmacies in my local vicinity so limiting medications from being shipped across state lines is unfair and unreasonable to me and other women in rural America.

I oppose the draft M.O.U. being proposed by the FDA and, in particular, object to the definition of "inordinate amount." Limiting the number of prescriptions that can be shipped out of state by a specialized pharmacy will restrict my ability to obtain medications that my doctor has prescribed for me and that are improving the quality of my life.

It is shameful in this country that large pharmaceutical companies haven't bothered to invest money into studies about hormone replacement therapy for women. Frankly, it is despicable that today's menopausal women are still guinea pigs when it comes to hormone replacement therapy. We're having to figure out for ourselves what to do when the standard medications don't work. One thing for certain is that our personal experiences are proving that one dosage of hormones does not fit all women's needs, and that hormones which have the same molecular structure as our bodies are better for most of us than those hormones that have been altered molecularly. It appears now that the larger pharmaceutical companies are realizing the error of their ways, and are using all their means to capture the market taken by the smaller, compounding pharmacies. Don't allow this to happen, please. Women need more choices not fewer.

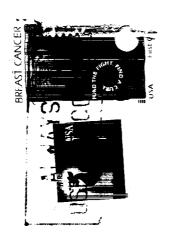
Sincerely,

Brenda Whitaker

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